

## REMARKS

Applicant, through the undersigned, wishes to thank Examiner Whiteman and Supervisory Examiner Burke for the courtesy and assistance extended on behalf of Applicant during a telephone interview conducted on March 31, 2005.

In the Final Action dated January 14, 2005, claims 16-30 are pending and under consideration. The Examiner has objected to the reissue declaration because the declaration does not state that all errors being corrected in the instant reissue declaration arose without deceptive intention. Claims 16-30 are objected to under 35 U.S.C. §251 as being based on a defective reissue declaration. The specification is objected to for allegedly failing to comply with the Sequence Rules. Claims 16-30 are objected to because of certain informalities.

This Response addresses each of the Examiner's objections and rejections. Accordingly, it is respectfully submitted that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Regarding the objection to the declaration, Applicant respectfully submits herewith a supplemental reissue declaration, which now states that all errors being corrected in the instant reissue declaration arose without deceptive intention on the part of Applicant. As such, withdrawal of the objection to the declaration and the rejection of claims 16-30 based on a defective declaration is therefore respectfully requested.

Regarding the objection to the specification, the Examiner states that the sequence that appears in Figure 2A is not listed in the Sequence Listing.

Applicant respectfully submits that the sequence depicted in Figure 2A is part of SEQ ID NO: 2. In fact, Figure 2A and Figure 2B, together, depict one single, continuous, double-stranded nucleic acid sequence. To clarify, Applicant has amended the drawing description to

recite that "Figure 2A and Figure 2B, joined at the match line", depict the double-stranded nucleotide sequence of SEQ ID NO: 2. As such, the objection to the specification is overcome. Withdrawal of the objection is respectfully requested.

Regarding the objection to the format of claims 16-30, the Examiner states that for each new claim added to the reissue application by the amendment being submitted, the entire text of the added claim must be completely underlined.

Accordingly, Applicant has represented the amendments to the claims, relative to the patent claims, in the format required under 37 C.F.R. §1.173. Furthermore, Applicant has presented in accordance with the provisions of 37 C.F.R. §1.173(c), on a separate page, the status of all patent claims and all added claims, as well as support for the changes made relative to the patent claims. Thus, the objection to the format of the claims is overcome. Withdrawal of the objection is therefore respectfully requested. Applicant is also providing a courtesy copy of the marked up version of the present claims, showing the changes made relative to the claims presented in the Preliminary Amendment dated July 16, 2003.

During the interview on March 31, 2005, the Examiner has also requested that Applicant explain the term, "a non-biologically functionally protein", as recited in claim 20. Applicant respectfully directs the Examiner's attention to col. 7, lines 15-19 of the specification, where non-biologically functionally proteins are described. Applicant respectfully submits that in light of the specification, the term is clear to those skilled in the art.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



Kenneth L. Cage  
Registration No. 26,151

McDermott, Will & Emery  
600 13<sup>th</sup> Street, N.W.  
Washington, D.C. 20005-3096  
Tel: (202) 756-8363

Date: May 12, 2005

Enc.: Supplemental Declaration; Marked-up Copy of Claims.

**MARKED-UP COPY – COURTESY ONLY. DO NOT ENTER.**

16. An expression vector comprising two inverted terminal repeats of adeno-associated virus 2 and at least one cassette comprising a promoter capable of effecting cell-specific expression, wherein each of said inverted terminal repeats is SEQ ID NO: 1 or a fragment of SEQ ID NO: 1 that comprises nucleotides 1 to 125 of SEQ ID NO: 1, wherein said promoter is operably linked to a heterologous gene, and wherein said cassette resides between said inverted terminal repeats.

17. The vector of claim 16 wherein each of said inverted terminal repeats ~~comprises the nucleotides of~~ is SEQ ID NO:1.

18. The vector of claim 16 wherein each of said inverted terminal repeats is a fragment of SEQ ID NO: 1 that comprises nucleotides 1 to 125 of SEQ ID NO:1.

19. The vector of claim 16 wherein said heterologous gene encodes a biologically functional protein.

20. The vector of claim 16 wherein said heterologous gene encodes a non-biologically functional protein.

21. The vector of claim 16 wherein said heterologous gene encodes an antisense RNA.

22. The vector of claim 16 wherein said heterologous gene is selected from the group consisting of a gene encoding  $\alpha$ -globin,  $\beta$ -globin,  $\gamma$ -globin, granulocyte macrophage-colony stimulating factor (GM-CSF), tumor necrosis factor (TNF), any one of interleukins 1-11, neomycin resistance, luciferase, adenine phosphoribosyl transferase (APRT), retinoblastoma, insulin, mast cell growth factor, p53, and adenosine deaminase.

23. The vector of claim 16 wherein said heterologous gene encodes P-glycoprotein.

24. The vector of claim 21 wherein said antisense RNA is complementary to a segment of the DNA or RNA encoding  $\alpha$ -globin.
25. The vector of claim 16 wherein said vector is AAV-B19-mdr.
26. A host cell transfected by the vector of any one of claims 16-25.
27. The host cell of claim 26 wherein said cell is a hematopoietic stem or hematopoietic progenitor cell.
28. A virion comprising the vector of any one of claims 16-24.
29. A host cell infected by the virion of claim 28.
30. The host cell of claim 29 wherein said cell is a hematopoietic stem or progenitor cell.